

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant:	Ruchika Singhal, Robert M. Skime and Carl D. Wahlstrand	Confirmation No.	6697
Serial No.:	10/731,868		
Filed:	December 09, 2003	Customer No.:	28863
Examiner:	William H. Matthews	Group Art Unit:	3774
Docket No.:	1023-330US01		
Title:	IMPLANTATION OF LOW-PROFILE IMPLANTABLE MEDICAL DEVICE		

CERTIFICATE UNDER 37 CFR 1.8 I hereby certify that this correspondence is being transmitted via the United States Patent and Trademark Office electronic filing system on March 1, 2010.

By:

Name: Patricia Cygan

REPLY BRIEF

Mail Stop: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is a Reply Brief responsive to the final Office Action dated March 31, 2009, the Advisory Action dated June 17, 2009 and the Examiner's Answer dated December 29, 2009. Accordingly, the due date for this Reply Brief is February 28, 2010 (Sunday) thereby extending to Monday, March 1, 2010.

No fees are believed to be due at this time. Please charge any additional fees that may be required or credit any overpayment to Deposit Account No. 50-1778.

ARGUMENT

In the Examiner's Answer to Appellant's Appeal Brief, the Examiner provided some new arguments in the section titled, "Response to Argument" beginning on page 5 of the Examiner's Answer. For brevity, this Reply Brief addresses these arguments only. Accordingly, this Reply Brief is not intended to address all arguments provided in the Examiner's Answer, and Appellant requests full consideration of all arguments as set forth in the Appeal Brief.

GROUP 1 - (Claims 12 and 27)

In the Examiner's Answer, the Examiner stated, "Applicant argued that the specification disclosure of 'placing the device or a portion thereof' supported the 'entire device' or 'a portion of the device' in the pocket and the Examiner agreed. Similarly, the scope of placing the device in the recess should be interpreted to include, or encompass placing the whole device in the recess and a portion in the pocket."¹

Appellant agrees that the language of claims 12 and 27 allow that the entire device might be placed in the pocket, but disagrees that claims 12 and 27 require the entire device to be placed in the pocket.

The Examiner apparently contended that Appellant's previous arguments can be used to narrowly construe, the feature of "placing the low-profile implantable medical device in the recess," as recited in claims 12 and 27, to mean placing the entire IMD in the recess. However, Appellant's previous arguments were related to the sentence, "The pocket may be opened sufficiently to receive IMD 12 or a portion thereof," as recited in paragraph [0022], to support the contention that the specification discloses placing all of IMD 12 in the pocket. As argued by the Appellant, in the context of "IMD 12 or a portion thereof," the phrase "IMD 12" must refer to all of IMD 12; otherwise the phrase "or a portion thereof" would have no meaning whatsoever. Such an argument is not applicable interpreting the feature of, "placing the low-profile implantable medical device in the recess" as recited by claims 12 and 27, as these claims do not include the phrase "or a portion thereof." For this reason, the Examiner's narrow interpretation of the feature of "placing the low-profile implantable medical device in the recess," as to mean placing the entire low-profile implantable medical device in the recess is improper.

¹ Examiner's Answer, page 6.

Claims 12 and 27 do not require placing the entire low-profile implantable medical device in the recess or in the pocket. Paragraph [0051] clearly provides written description support for placing all of an IMD or less than all of the IMD (e.g., one or more modules) within a recess. Because claims 12 and 27 allow that the portions of the IMD may be located in a recess that is only formed the exposed region of the skull and an adjacent pocket, the Examiner's statement that, "one of ordinary skill in the art would expect a recess to be formed in an exposed region of the skull (i.e. outside the claimed pocket),"² does not directly support the written description rejection of claims 12 and 27. The Examiner failed to provide any other substantive explanation as to why a person of ordinary skill in the art would not recognize in Appellant's disclosure a description of the invention of claims 12 and 27.

The Examiner failed to meet the initial burden of presenting by a preponderance of evidence why a person of ordinary skill in the art would not recognize in an Appellant's disclosure a description of the invention defined by the claims.³ The combination of using a pocket (as recited in independent claims 1 and 26) and a recess (as recited in claims 12 and 27) is clearly supported by Appellant's specification as filed. For these additional reasons, the Examiner's rejection of claims 12 and 27 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement is in error. Reversal of this rejection is requested.

GROUP 3 - (Claims 1-7, 9-11, 15, 17, 24 and 30)

In the Examiner's Answer, the Examiner stated that, "column 29, lines 21-48 clearly describe the distinctions between placement of wires 612/613 versus wire 616." However, the distinctions between placement of wires 612/613 versus wire 616 in column 29, lines 21-48 of Fishcell are referred to by the Examiner as simply, "sometimes running most of the wire length between the scalp and the cranium and at other time running most of the wire length between the bottom of the cranium and the dura matter."⁴

This teaching does not contradict the teaching in Fishcell that wires are *tunneled under the scalp* to burr holes, e.g., as shown in FIGS. 15 and 16 and described in column 29, lines 21-

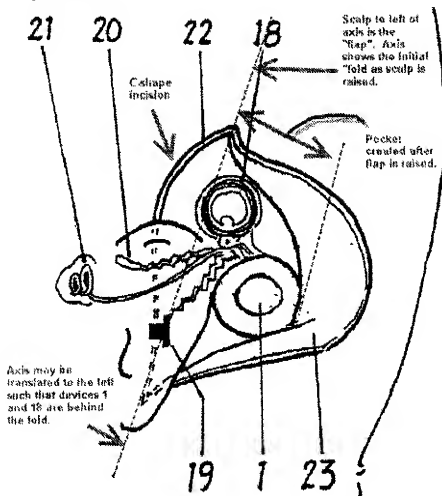
² Final Office Action dated March 31, 2009, page 2.

³ *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976).

⁴ Fishcell, column 29, lines 28-31.

48, as described in the Appellant's first Brief on Appeal. As also described in the Appellant's first Brief on Appeal, MPEP 2125 precludes relying upon proportions of features shown in a drawing absent evidence that the drawings are to scale, and the proportions shown in Fischell, FIG. 15 can not be used to overcome the description in Fischell, column 29, lines 21-48, which clearly teaches wires are tunneled under the scalp to burr holes. Accordingly, Appellant maintains that Fischell fails to teach or suggests drilling a burr hole in a portion of a skull under a scalp flap that is also used to implant a low-profile medical device.

In addition, Appellant objects to the Examiner's reliance on the figure shown on page 10 of the Examiner's Answer from the disclosures of Berrang and Berrang Application with respect to the features of creating a pocket adjacent to the fold and between the scalp and the skull as recited in Appellant's claims. For reference, the figure shown on page 10 of the Examiner's Answer is reproduced below.



The rejection relies upon the figure shown above as providing an accurate depiction of a patient during an implant procedure. However, the figure is only an illustrative representation of an implantation procedure, and does not accurately depict the scalp flap. Specifically, the figure above illustrates the scalp flap in an impossible position. The length of the scalp incision on the left is depicted as being much shorter than the length of the scalp adjacent the incision on the right (i.e. the edge of the scalp flap). If the figure reproduced by the Examiner on page 10 of the Examiner's Answer were an accurate representation of a patient's scalp during implantation of a cochlear implant, then the patient's scalp should be approximately the same length on both sides of the incision. The disparity means that the figure reproduced by the Examiner on page 10 of the Examiner's Answer merely includes an artistic illustration of the patient's scalp during the implant procedure, and can not reasonably be relied upon as disclosing a both a flap and a pocket as recited in Appellant's claims.

For these additional reasons, Applicant maintains that the rejection of claims 1-7, 9-11, 15, 17, 24 and 30 is improper and should be reversed.

GROUP 6 - (Claim 25)

In the Examiner's Answer, the Examiner argued that, despite the clear language of claim 25, the feature of "placing all of the low-profile implantable medical device in the pocket" as recited in claim 25 does not in fact mean placing all of the low-profile implantable medical device in the pocket. The Examiner argued that it instead means placing some of the low-profile implantable medical device in the pocket. In support of this absurd interpretation, the Examiner noted that the leads may extend outside the pocket. However, claim 1 distinguishes between the low-profile implantable medical device and the leads. Claim 1 does not say that the "one or more leads" are part of the low-profile implantable medical device; therefore, the feature of "placing all of the low-profile implantable medical device in the pocket" as recited in claim 25 does not relate to the placement of the leads. In this manner, the location of the leads is not relevant to the feature of "placing all of the low-profile implantable medical device in the pocket."

For these additional reasons, Applicant maintains that the rejection of claim 25 is improper and should be reversed.

GROUP 10 -- (Claims 28 and 32)

Appellant objects to the Examiner's reliance on the figure shown on page 10 of the Examiner's Answer from the disclosures of Berrang and Berrang Application with respect to the features of creating a pocket adjacent to the fold and between the scalp and the skull as recited in Appellant's claim 28. The rejection relied upon the figure as providing an accurate depiction of a patient during an implant procedure. As mentioned with respect to Group 3 above, the figure is only an illustrative representation of an implantation procedure, and does not accurately depict the scalp flap. The figure reproduced by the Examiner on page 10 of the Examiner's Answer merely includes an artistic illustration of the patient's scalp during the implant procedure and can not reasonably be relied upon as disclosing the creation of both flap and a pocket as recited in claim 28.

For these additional reasons, Applicant maintains that the rejection of claims 28 and 32 is improper and should be reversed.

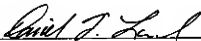
CONCLUSION

All claims in this application are in condition for allowance. Appellant respectfully requests the Board promptly withdraw each of the rejections and place the application in condition for immediate allowance reasons addressed above as well as the reasons set out in the Appeal Brief.

Respectfully submitted,

Date: March 1, 2010

By:



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